

Remarks/Arguments:

Claims 1, 3-11, 14-21 stand rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regard as the invention. Specifically the Examiner objects to the use of the term “about.” Applicants respectfully traverse this rejection and respectfully request withdrawal of the same. Applicants have amended the claims and the amendment renders this rejection moot.

Claims 1, 3-11, 14-21 stand rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regard as the invention. Specifically the Examiner objects to lower range of the claim since it would allow the total percentage of components to be 42.4%. Applicants respectfully traverse this rejection and respectfully request withdrawal of the same. Applicants have amended the claims and the amendment renders this rejection moot.

Claim 7 is rejected as the phrase “the solution” lacks antecedent basis. The claim has been amended and the amendment renders the rejection moot.

Claim 9 is rejected as the term “the solvent” lacks antecedent basis. Claims 8 and 9 have been amended and the amendment renders this rejection moot.

Claim 16 is rejected as the phrase “the solution” lacks antecedent basis. The claim has been amended and the amendment renders the rejection moot.

Claim 17, line 5, has been amended to correct the typographical error.

Claim 18 is rejected as the phrase “the solution” lacks antecedent basis. The claim has been amended and the amendment renders the rejection moot.

Claim 21 is rejected as the phrase “the solution” lacks antecedent basis. The claim has been amended and the amendment renders the rejection moot.

Claims 1, 3-11, and 14-21 are rejected under 35 U.S.C. §103 as being unpatentable over Sham (WO 97/21685) in view of Yamamoto (US5264223) and Yamamoto (US5756123). Specifically, the Examiner maintains that Sham discloses the invention substantially except for the presence of water. Yamamoto discloses capsules that contain water. Applicants traverse this rejection and respectfully request withdrawal of the same.

The addition of water to the claimed composition is the essence of this invention. The compositions of the instant invention provide greatly improved solubility for HIV protease inhibiting compounds contained therein when compared to analogous compositions without

added water. This increase in solubility would not be expected as the protease inhibitors claimed in the instant invention have very low solubility in water. Ideally, if the polarity of a compound and the solvent is roughly equal then the compound will dissolve well. The protease inhibitors of the instant invention and water have significantly different polarities. Therefore, the increased solubility of the compositions (see figures 3-7 and examples 8, 9, and 10) with the addition of water would not be predicted or expected.

The Examiner cites Yamamoto in combination with Sham to show that it was known in the art that capsules could contain water in a range of 1-6%. However, Yamamoto teaches that the % water in a hard capsule can be decreased from the known 10-15% and that the decrease in % water was desirable since drugs were often decomposed by the higher % of water in the capsule. Yamamoto does not teach the addition of water to increase the solubility and in turn the bioavailability of pharmaceutical compositions. Thus, the problem corrected by the Applicants of the instant application, the poor solubility of protease inhibiting compositions, was not addressed and has no relation to the teachings of Yamamoto. The teachings of Yamamoto are irrelevant to the problem solved by Applicants and would not provide any motivation to combine the teachings.

Hence, Applicants respectfully maintain that Yamamoto cannot cure the deficiencies of the Examiner's 103 rejection. Applicants request withdrawal of this rejection.

Claims 1, 2-11, 14-21 stand rejected under 35 U.S.C. §103 as being unpatentable over Razzak (US5948436). Applicants respectfully traverse this rejection and respectfully request withdrawal of the same. The Examiner argues that Al-Razzak et al. teaches the elements of the claimed invention. The Examiner then notes that Applicants have stated that the disclosed compositions do not contain fatty acids, and contends that while the disclosed compositions do not contain free fatty acids, they contain fatty acids nonetheless and points to Col. 6, lines 50+. Again, this is not the case.

The Examiner points to in Col. 6, lines 50+ which describes a component named Gelucire® which is not a fatty acid. It is true that when Gelucire is characterized and broken down into its most basic components fatty acids can be obtained. However, Gelucire® consists of mono-, di- and triglycerides and polyethylene glycol mono- and di-esters. The Examiner's deconstruction or cleavage of Gelucire® and, more particularly, the mono-, di- and triglycerides as well as the mono- and di-fatty acid esters, into their subcomponents cannot stand. Therefore,

the instant invention is distinguishable from Razzak. Applicants respectfully request this rejection be removed.

CONCLUSION

Applicants maintain that the claims are now in condition for allowance, and respectfully request the Examiner to allow same. Support for the amendments can be found throughout the specification. In order to advance the prosecution of this case, Applicants have incorporated many of the Examiner's suggestions into the newly amended claims, and invite the Examiner to a teleconference to resolve any other issues which the Examiner may have.

A three month extension is deemed necessary by the Applicants.

Respectfully submitted,
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